



Docket No.: 246789US23

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313



ATTORNEYS AT LAW

J. DEREK MASON
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RE: Application Serial No.: 10/813,017

Applicants: William J. LAHL

Filing Date: March 31, 2004

For: POLICOSANOL COMPOSITION AND ITS USE IN
TREATMENT OF HYPERCHOLESTEROLEMIA

Group Art Unit: 1614

Examiner:

SIR:

Attached hereto for filing are the following papers:

Applicants Additional Information Disclosure Statement
Information Disclosure Statement
PTO Form 1449
References (40)

Our check in the amount of -0- is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

J. Derek Mason, Ph. D.

Registration No. 35,270

Customer Number

22850

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DOCKET NO: 246789US23

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :
WILLIAM J. LAHL : EXAMINER:
SERIAL NO: 10/813,017 :
FILED: MARCH 31, 2004 : GROUP ART UNIT: 1614
FOR: POLICOSANOL COMPOSITION :
AND ITS USE IN TREATMENT OF
HYPERCHOLESTEROLEMIA

APPLICANTS ADDITIONAL INFORMATION DISCLOSURE STATEMENT

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Prior to examination on the merits, Applicants provide herewith an information disclosure statement providing various published documents and information regarding activities prior to the filing date of the present application.

Beginning in about 2001, Applicants began seeking a policosanol product that they could market. Attached are copies of literature or letters regarding several products that were available prior to the present application being filed. In a letter dated July 14, 2001, the company SuanFarma was offering a product containing 90% octacosanol. In a second document (undated, but prior to the present application filing) from a company named Garuda International, Inc. a policosanol product (LESSTANOL) was offered containing approximately 58% of octacosanol, along with an email dated July 31, 2001 from Garuda identifying this product as OCTA-60, and also offering a product called OCTA-95, which was 95% octacosanol. A third company, Cyvex Nutrition, Inc. was at approximately the

same time (2001-2002) offering a product named BENECOSANOL 50, made from rice, which contained approximately 50-60% octacosanol, as demonstrated by the product specification and the monograph regarding the product provided herewith. Further, Cyvex Nutrition was promoting their BENECOSANOL 50 product for treatment of hypercholesterolemia.

The surprising results obtained using the present invention policosanols vs. policosanols containing approximately 60% octacosanol as in these prior commercially available products is discussed in the present application at page 4, beginning at line 21.

The present Applicants began working with a Chinese supplier to develop a policosanols product that would be obtained from rice bran wax, and would contain only 25-35% of octacosanol, initially to provide a more cost-effective policosanols product. Various batches were made of various ultimate compositions during the period from 2001 to approximately April 2003. During that period, some batches were sold in small quantities (from 1-3 kg typically, with one sale of 6 kg in October 29, 2001, as shown in the attached listing of Batch Sales) for evaluation by potential customers. However, during this period, the formulation was not finalized, and was still being evaluated by those purchasing the samples. To Applicants' understanding, the purchasers of these experimental batches were using the batches in formulations where the policosanols was an extremely minor ingredient.

Further, until April 2003, the policosanols composition being sampled to potential customers by the Applicants was highly variable, and no final formulation or method to obtain it had been arrived at. In approximately April 2003, the Applicants arrived at a final formulation, which was thus "ready for patenting" in accordance with the test for on-sale according to *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998). This final formulation also met the present application claims, and Applicants began marketing this final product in earnest. The present application was filed less than one year after the final formulation was

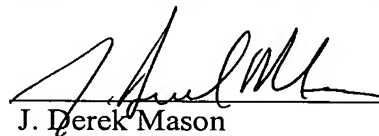
Application No. 10/813,017
Information Disclosure Statement

arrived at and then offered for sale. Accordingly it is not believed that the prior activity is sufficient to act as a bar under 35 U.S.C. 102(b).

Consideration of this information and the accompanying documents is respectfully requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

A handwritten signature in black ink, appearing to read "J. Derek Mason", is written over a horizontal line.

J. Derek Mason
Attorney of Record
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(OSMMN 06/04)



Docket No.

246789US23

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: William J. LAHL

SERIAL NO: 10/813,017

GAU: 1614

FILED: March 31, 2004

EXAMINER:

FOR: POLICOSANOL COMPOSITION AND ITS USE IN TREATMENT OF HYPERCHOLESTEROLEMIA

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

REFERENCES

- ☒ The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

RELATED CASES

- ☐ Attached is a list of applicant's pending application(s), published application(s) or issued patent(s) which may be related to the present application. In accordance with the waiver of 37 CFR 1.98 dated September 21, 2004, copies of the cited pending applications are not provided. Cited published and/or issued patents, if any, are listed on the attached PTO form 1449.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

CERTIFICATION

- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

DEPOSIT ACCOUNT

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

J. Derek Mason, Ph. D.

Registration No. 35,270

Customer Number

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Form PTO 1449 (Modified)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO. 246789US23		SERIAL NO. 10/813,017	
LIST OF REFERENCES CITED BY APPLICANT				APPLICANT William J. LAHL			
				FILING DATE March 31, 2004		GROUP	
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	AAA	garuda INTERNATIONAL, INC., "LESSTANOL brand Policosanol (Derived from Natural Vegetable Sources), Product Code, OCTA-60, Manufacture date: September 14, 2001, Expiry Date, September 13, 2003, Lot Number 888-0-1284-FF.					
	AAB	Letter dated Saturday, July 14, 2001 to Mr. William J. Lahl, Ph. D. Marcor From Gonzalo Marin, SUANFARMA					
	AAC	POLICOSANOL DATA SHEET, RAIN LABS, S.A., Product Name Policosanol 5 mg. capsules.					
	AAD	The Natural PHARMACIST, TNP.com, webpage article, Herbs & Supplements: Policosanol, 6/24/01.					
	AAE	"POLICOSANOL, Monograph, webpage www.policosanol.com/monograph.htm, 06/05/01.					
	AAF	Webpage, Nature's Nutrition Store, http://shop.store.yahoo.com/naturenutrition-ca/3388.html., 03/27/02.					
	AAG	webpage www.hcrc.org/faqs/octacos.html, 12/26/0, Health Care Reality Check, (HCRC) FAQ Sheet, Octacosanol, Ellen Coleman, RD, MA, MPH.					
	AAH	Webpage www.tnp.com/news/article/396, printed 12/05/01. The Natural PHARMACIST TNP.com, Article 11/26/01, Policosanol: Beeswax Versus Sugarcane, Steven Bratmen, M.D.					
	AAI	Webpage www.rainlabs.com/ingels/plantas/policosanol.htm, POLICOSANOL Policosanol CAPSULES Basic INformation, printed 06/24/01.					
	AAJ	Webpage article, www.usatoday.com/news/healthscience/health/2001-08-20-statin.htm, USA TODAY, Health & Science, Warning labels urged for cholesterol drugs, Steve Sternberg, webpage printed , 04/18/02.					
	AAK	Webpage article, www.policosanol.com, Policosanol, BioMedica Natural PProducts, Inc. printed 03/27/02.					
	AAL	Webpage article, www.bpfuture.com/cholestin, Pharmanex: Provided by Nature, Proven by Science, Cholestin, Healthcare Product Guide, Printed 03/27/02.					
	AAM	Webpage article, www.life-enhancement.com/displayart.asp?ID=640, LIFE enhancement, PoliChol and the New CholestOut II Both contain Policosanol					
	AAN	Webpage article, www.nutraceuticalingredients.com/policosanol.htm, printed 03/27/02, AHD International, LLC, Policosanol					
	AAO	Sid Shastri, Policosanol: The New Natural Cholesterol Fighter, Vitamin Retailer, July 2002, pp.38-40.					
	AAP						
	AAQ						
Examiner				Date Considered			
*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	AAA	Webpage article, www.bpfuture.com/cholestin/ , Pharmanex: Provided by Nature, Proven by Science, Cholestin, Healthcare Product Guide					
	AAB	Webpage article, www.health-pages.com/ry/ , Whole Health Discount Center, CHOL-X Replaces Red Yeast Rice, printed 09/27/02					
	AAC	Webpage article, www.life-enhancement.com/displayart.asp?ID=593 , The Science Behind The Products LIFE enhancement, New PoliChol, a Sugar Cane Extract, Can Lower Your Cholesterol Levels, Policosanol As Powerful as Statins for Lowering Cholesterol Levels, printed 04/18/02.					
	AAD	Webpage article, http://stores.yahoo.com/naturenutrition-ca/3388.html , Nature's Nutrition Store, Vitamins and Supplements at Discount Prices, Policosanol.					
	AAE	Webpage article, www.tnp.com/substance.asp?ID=1000 , The Natural PHARMACIST TNP.com, Herbs & Supplements: Policosanol, printed 06/04/01					
	AAF	Webpage article, www.cholesterolcheck.org/policosan.htm , POLICOSANOL, Cholesterol Test Kits, printed 04/18/02					
	AAG	HEALTHCARE PROFESSIONALS PRODUCT GUIDE, CHOLESTIN®, (11 pps.)					
	AAH	T.S. Kahlon, et al., Cholesterol-Lowering by Rice Bran and Rice Bran Oil Unsaponifiable Matter in Hamsters, Vol. 73, No. 1, 1996, pp 69-74.					
	AAI	Webpage article, www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10c... ; printed 08/17/01, Int J. Clin Pharmacol Res 1999;19(4):117-27, "Comparative study of the efficacy and tolerability of policosanol and lovastatin in patients with hypercholesterolemia and noninsulin dependent diabetes mellitus.", Crespo N, et al.					
	AAJ	Webpage article, www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=112... Printed 08/17/01, J Gerontol A Biol Sci Med Sci 2001 Mar;56(3):M186-92, Castano G, et al., Effects of policosanol in older patients with type II hypercholesterolemia and high coronary risk.					
	AAK	Webpage article, www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12099160&dopt=... , printed 06/11/03, Drugs R D. 2002;3(3):159-72., Effects of policosanol on older patients with hypertension and type II hypercholesterolaemia., Castano G, et al., Surgical Medical Research Center, Havana City, Cuba.					
	AAL	Michael Yalcilla, Ph.D., Senior Scientist Technica Consumer Health Hayward, Ca., www.nutraceuticalsworld.com , Nutraceuticals World, April 2002, pp. 28-34.					
	AAM	AHD INTERNATIONAL, LLC, Product Data Sheet POLICOSANOL					
	AAN	Webpage article, "Cholestin Reformulated", www.nutraceuticalsworld.com , Nutraceuticals World, April 2002, pg 34 and pg 29.					
	AAO	Webpage article, www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9772... , printed 05/08/02, Ahongguo Zhong Yao Za Zhi 1996 Sep;21(9):553-4,576, [Active constituents lowering blood-lipid in beeswax], Liu F, Sun D.					
	AAP	Webpage article, www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=1183... , printed 05/08/02, Am Heart J 2002 Feb;143(2):356-65, Gouni-Berthold I, Berthold HK, "Policosanol:clinical pharmacology and therapeutic significance of a new lipid-lowering agent.					
	AAQ	Webpage article, www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=1120... , printed 05/08/02, Ter Arkh 2000;72(12):7-10, [Results of the multicenter controlled study of the hypolipidemic drug policosanol in Russia], Nikitin IuP, et al.					
Examiner				Date Considered			
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	AAA	Healthcare Professional Product Guide, Cholestine, A Scientific Product Review, Standardized Policosanol Extract, PHARMANEX.					
	AAB	Webpage article, printed 12/05/01, www.healingpeople.com/hp_html/primapub/gp000239.htm, Herbs & Supplements: Octacosanol					
	AAC	Webpage article, www.ehealthcenter.com/cgi-bin/ehealth/bventry.jsp?keyValue=products&keyTopic=...printed,12-05-01, "New Cholesterol Guidelines-=New Cholestin".					
	AAD	Kazuko Kawanishi, et al., "Free Primary Alcohols in Oils and Waxes from Germs, Kernels and Other components of Nuts, Seeds, Fruits and Cereals, JAOCS, Vol 68, no. 11 (November 1991), pps. 869-872.					
	AAE						
	AAF						
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	AAH						
	AAI						
	AAJ						
	AAK						
	AAL						
	AAM						
	AAN						
	AAO						
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